

TAB D



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: December 17, 1997

TO : Val H. Schaeffer, Ph.D.
Project Manager
EHHE

Through: Alan H. Schoem, Assistant Executive Director, EXC *AHS*
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FROM : Michael T. Bogumill *MTB*
Compliance Officer
CRM

SUBJECT: Special Packaging of Oral Prescription Drugs in Dropper Bottles.

PURPOSE: To set forth the historical position that the Office of Compliance has taken on eye droppers that accompany liquid medication packages which are subject to a rule or standard under the Poison Prevention Packaging Act (PPPA).

DISCUSSION: Since at least 1974,^{1,2} the Office of Compliance has taken the position that if a package containing liquid medication is required to be child-resistant pursuant to a rule under 16 C.F.R. § 1700.14(a) [e.g., a liquid acetaminophen preparation containing more than 1,000 mg of the drug in a single package § 1700.14(a)(16)] a dropper assembly accompanying the package must incorporate a feature that renders the reservoir bottle/dropper assembly combination child-resistant. If the dropper fails to incorporate a child-resistant feature, the staff position is that the dropper cannot incorporate a feature (e.g. a threaded closure) that can be used to secure the contents of the reservoir bottle. This position effectuates the requirement of the Poison Prevention Packaging Act requirements that a child-resistant package must remain child resistant for the normally expected number of openings and closings of the package until its contents are consumed. 16 C.F.R. § 1700.15.

¹ Letter to Alfred J. Duncan, Executive Secretary of the Arizona State Board of Pharmacy from Robert G. Poth, CPSC Bureau of Compliance, April 11, 1974.

² CPSC Memorandum from D.S. Lemberg, Office of General Counsel and R.G. Poth, Bureau of Compliance, June 12, 1974.

This position has been conveyed to industry a number of times over the last twenty-three years. Compliance staff believe it to be a reasonable position. In addition, the regulated industry appears generally to accept this position and meets the intended child-resistant requirements with the affected regulated products.